AWARD NUMBER: W81XWH-14-2-0128

TITLE: Safety and Efficacy of the BrainPort V100 Device in Individuals Blinded by Traumatic Injury

PRINCIPAL INVESTIGATOR: Patricia Grant, M.S.

CONTRACTING ORGANIZATION: Wicab, Inc.
Middleton, WI 53562

REPORT DATE: December 2016

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
December 2016	Final	25 Sep 2014 - 24 Sep 2016

4. TITLE AND SUBTITLE

Safety and Efficacy of the BrainPort V100 Device in Individuals Blinded by Traumatic Injury

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-2-0128

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Patricia Grant, M.S. pgrant@wicab.com
Rich Hogle, M.S. rhogle@wicab.com

5d. PROJECT NUMBER
0010378679USA

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

WICAB, INC
8313 GREENWAY BLVD STE 100
MIDDLETON WI 53562-3500

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This study is a prospective, single-arm, multicenter clinical investigation. The aim of this study is to evaluate the functional performance of the BrainPort® V200 device, a non-surgical, FDA approved, sensory substitution system, in persons who are profoundly blind due to a traumatic injury (cortical or ocular). The device, which provides visual information via electrotactile stimulation on the tongue, is designed to enhance independence in performing activities of daily life. Nine out of the 20 projected participants have been enrolled across study sites. Participants have received ten hours of device training and have taken the device home to use in their everyday environments for the next 12 months. Functional performance measures of object identification, place setting identification, orientation and mobility, and word identification were assessed at baseline and post-device training. Follow-up assessments will be completed at 3, 6, 9, and 12 months. The psychosocial impact of assistive devices and general self-efficacy were assessed at baseline and will be measured a second time at the end of the study. Device-related adverse events will be reported throughout the study to evaluate the risks associated with the BrainPort V200. The remaining 11 participants have been recruited and will be enrolled within the next quarter.

15. SUBJECT TERMS
BrainPort, V100, V200, blindness, visual impairment, assistive device, assistive technology, visual aid, non-surgical visual prosthetic, sensory substitution

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	11	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. INTRODUCTION:

The BrainPort V200 device is a wearable, non-surgical, FDA approved, prosthetic device intended for people who are profoundly blind. The BrainPort V200 translates images captured by a digital camera into electrotactile stimulation presented on the user's tongue to perceive shape, size, location, and motion of objects within the environment. The purpose of this study is to evaluate the safety and functional performance of the BrainPort V200 in individuals who have been medically documented as blind, light perception or worse, due to a traumatic injury (cortical or ocular).

2. KEYWORDS:

BrainPort, V100, V200, blindness, visual impairment, assistive device, assistive technology, visual aid, non-surgical visual prosthetic, sensory substitution

3. ACCOMPLISHMENTS:

What were the major goals and objectives of the project?

The major goals of this research project are to evaluate the safety and effectiveness of the BrainPort V200 device in individuals who have been blinded by traumatic injury by enabling this population to use and evaluate the BrainPort V200 device in normal operational settings, including at home and in public places. An additional objective of this study is to explore the design and hardware requirements for a population with multiple disabilities (polytrauma). The aim is that the findings from this research will result in a proven assistive technology ready for rapid deployment to wounded warriors, veterans, and civilians who have been blinded by traumatic events.

What was accomplished under these goals?

Specific Aim 1: Enable individuals blinded by traumatic injury to test and evaluate the BrainPort V200 device in normal operational settings (at home, public places, etc).

<u>Device and Software Development</u>

While the first year of development of the BrainPort V200 device (Figure 1), the engineering activities in the second year of the study included bug fixes, the SignFinder application installation, and software upgrades following subjects' 6 month assessment visits.

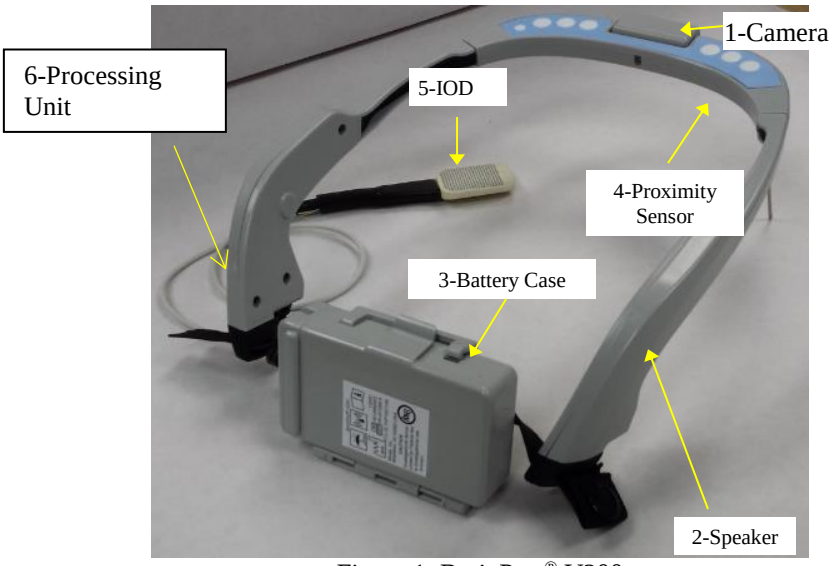


Figure 1: BrainPort® V200

The 'SignFinder' application assists the subjects in locating important signs commonly found in a public setting, specifically EXIT, MEN'S ROOM, and WOMEN'S ROOM signs. Following the subjects' 6 month visit, the devices were sent back to the Wicab, Inc. site for upgrades and returned to the subjects' homes (approximately 2 weeks following their assessment visit). The software upgrades include audio feedback during power up/down process, image invert software fix, improved battery status reporting, headset arms improved, and user controls improved. These upgrades were further detailed in the Y2Q2 technical report.

Specific Aim 2: Evaluate the safety and efficacy of the BrainPort V200 device on this population.

Subject Enrollment

To date 22, subjects have been enrolled in the study (14 from Chicago Lighthouse and 8 from Lighthouse Guild). Of these 22 subjects, four are Veterans. To date, four of these subjects have withdrawn from the study dues to reasons of lack of interest in the device or study activities. The subject characteristics for the total study sample are located in Table 1.

Table 1. Subject Characteristics (n=22)

Age (years)		**Duration of Blindness** (years)	
Mean ± SD	40.68 ± 12.32	Mean ± SD (N)	30.8 ± 22.5
[Median] (min, max)	[40.5] (21.0, 66.0)	[Median] (min, max)	[8.5] (1.0, 56.0)
Gender % (n)		**Braille Readers**	63.6% (14)
Women	23% (5)	**Mobility Assistive Device**	
Men	77% (17)	Use Any Type	100% (22)
Race % (n)		White Cane	100% (22)
American Indian /Alaska Native	0% (0)	Guide Dog	27% (6)
Black or African American	45.45% (10)	Sighted Guide	50% (11)
Other	9.1% (2)		
White	45.45% (10)		
Ethnicity			
Hispanic or Latino	9.1% (2)		
Not Hispanic or Latino	90.9% (20)		

Subject Follow-Up

All 18 subjects who are currently enrolled are in the home usage and follow-up phase of the study. The subjects are expected to use the device for a total of 300 minutes per month and return to the study site every 3 months to undergo assessment testing. In addition, study staff calls administers bimonthly phone calls to troubleshoot problems, encourage subjects to continue to use the device for the required minutes, and assess for adverse events.

All subjects were given access to the online blog at CafePress.com where they can anonymously discuss usage at home with other subjects, share feedback, troubleshooting tips, and offer suggestions for use and device improvement. The site is continuously monitored by the PI.

The study staff trained subjects on how to use the SignFinder application during their 6 month assessment so that they are prepared to use the application in their own environments and at the study sites during their 9 month assessment visits. Assessment on the application will be conducted during subjects' 9 month assessment visits.

Interim Results – 6 month quarterly assessment

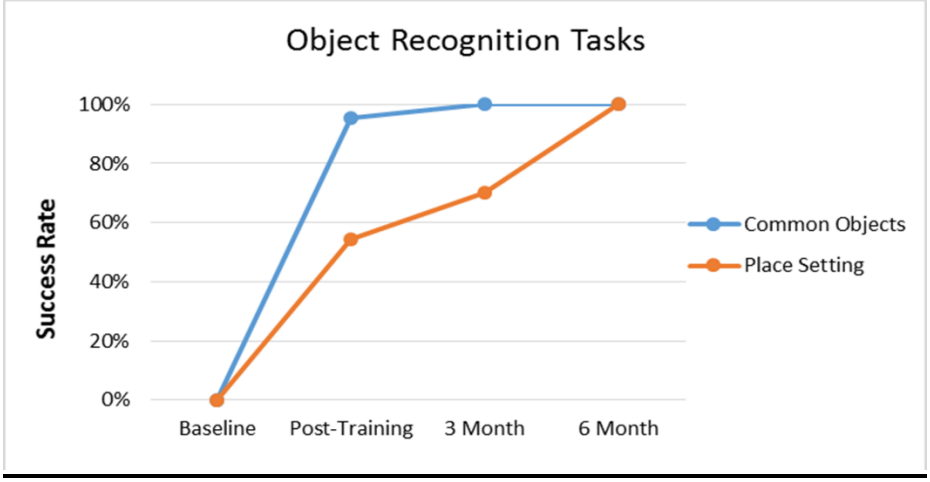
Safety Objective: To date, no clinically significant device related adverse events have been reported. Therefore our safety objective has been met at the 6 month time point.

Object Recognition Tasks (Common Objects and Placing Setting Objects): Four high contrast objects are placed on a table 10" apart. The subjects are instructed to use the BrainPort V200 device to identify the object and then grab the target object without touching any other objects first. The objects in the common objects task include a ball, banana, mug, and spoon. The objects in the place setting task include a plate, bowl, glass, and fork. The assessment is deemed as successful if the subject is able to identify five or more objects out of ten trials.

Object Recognition Tasks Results

At baseline, none of the subjects were able to perform either task successfully without the use of the BrainPort V200 device. At 6 months, 100% of the subjects could achieve these 2 tasks beyond chance level, therefore our efficacy objective has been met at the 6 month time point (Figure 2).

Figure 2. Object recognition task success from baseline through 6 months (n=18)



Reading Tasks

The following reading tasks were administered:

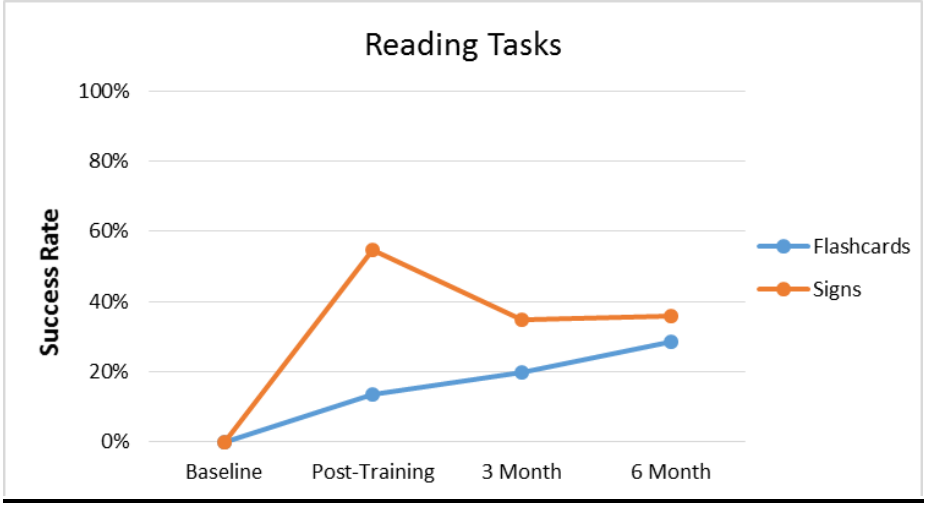
Flashcards: Ten 3-6 letter words were presented on a standard size flashcard. Subjects were instructed to use the BrainPort V200 to read the words aloud. Successfully reading greater than 5 out of 10 words represents success beyond chance.

Sign Detection: This task consisted of a combination of reading and mobility tasks. Four signs were hung in a 20' hallway. Subjects were asked to navigate independently down the hallway and identify and touch the target sign. If the subject touched or came within 5" of touching the target sign, this was recorded as a successful trial. The signs included MEN, WOMEN, STAIRS, and DANGER.

Reading Tasks Results

None of the subjects were able to successfully complete either reading task at baseline, without the use of the BrainPort V200. At the 6 month assessment period, 29% of the subjects were able to complete the flashcard reading task and 38% of subjects are able to complete the Sign ID task (Figure 3).

Figure 3. Reading tasks success rates from baseline through 6 months (n=18)



Orientation and Mobility Tasks

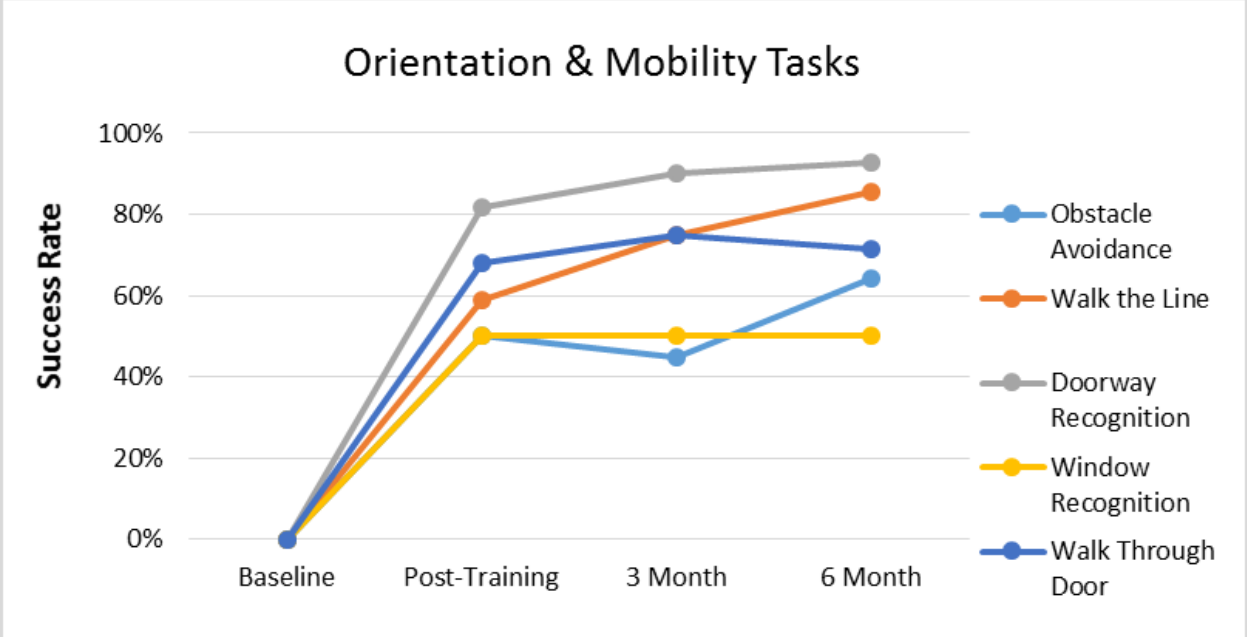
The orientation and mobility assessment includes several tasks consisting of the following:

- •Following a high contrast line on the floor without veering off
- •Identifying and avoiding an obstacle in their pathway
- •Identifying a window and door in the room
- •Walking through the doorway without colliding with the doorframe.

Orientation and Mobility Results

Similar to other tasks, none of the subjects were able to successfully complete the orientation and mobility tasks at baseline without the BrainPort V200 device. At 6 months, 87% of subject could follow a line without veering off, 64% could identify and avoid an obstacle in their pathway, 93% could recognize a door in the room, 71% could walk through the door without colliding with the doorframe, and 50% could recognize a window in the room. The success rates for baseline, post-training, 3 months, and 6 months are displayed in Figure 4.

Figure 4. Orientation and mobility success rates from baseline through 6 months (n=18)



FITBIR

The FITBIR form structures for all study data have been created and a data submission is planned for February/March 2017.

IRB Status

The New England IRB approved continuation of the study at all three study sites from the dates of 10/25/2016 – 11/22/2017. The HRPO has been notified of approval.

What opportunities for training and professional development did the project provide?

The study activities undertaken by Research Associate Tiffany Arango under the direction of Dr. William Seiple at the Lighthouse Guild contributed to her professional growth in the areas of developing research skills through interactions with the site PI, study PI, and research subjects and participating in the successful management of a research agenda. Enhancement of these skills has prepared her for acceptance to the PhD program in the Psychology Department at Northeastern University for the Fall term 2016.

How were the results disseminated to communities of interest?

The 6 month interim results of this study were presented at the U.S. Department of Veterans Blind Rehabilitation Services National Convention in August 2016 in Milwaukee, WI. Attendees of the presentation included Blind Rehabilitation Outpatient Specialists, Visual Impairment Services Team Coordinators, and other BRS staff from the VA Central Office. The presentation fostered further communications surrounding provision of the BrainPort training in VA Hospitals and BRS Centers. The implementation of BrainPort training is expected to begin at the Central Blind Rehabilitation Center at the Edward Hines Jr. VA Hospital in the near future.

What do you plan to do during the next reporting period to accomplish the goals and objectives?

The main effort for the next reporting period is to complete all 9 month quarterly assessments and begin 12 month quarterly assessments. The expected achievements for the next reporting period are detailed in Table 1.

Table 1. Scheduled achievements for Year 2- 4th Quarter

Major Task	SubTask
1. Human subject protocol and informed consent	• Continue to monitor for adverse events to report to the IRB.
2. Site Training	• Assure study staff maintains human subjects training for remainder of study.
3. Participant Recruitment and Evaluation	• Complete 9 month quarterly assessments on begin final assessments.
4. Coordinate safety and efficacy reporting	• Monitor study data and communicate with study sites for reports of adverse events. • Monitor social networking website to review feedback from participants regarding device use.
5. Data Analysis	• FITBIR data download is planned for February 2017. • Coordinate with study sites to disseminate study findings at the Association for Research in Vision and Ophthalmology 2017 annual meeting.

4. IMPACT

To date, study participants have been given the opportunity experience the device in their personal settings and provide valuable feedback on device usage which has contributed to the overall design of the BrainPort V200 device. Our interim results indicate that participants are able to successfully engage in activities of daily living such as object recognition, text identification, and orientation and mobility tasks.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change
Nothing to report to during this reporting period

Actual or anticipated problems or delays and actions or plans to resolve them
As noted in Wicab's letter to CDMRP dated August 25, 2016, we are currently delayed in completion of the study by approximately 6 months. Our letter served as notification to a 12-month extension and reallocation of funds.

Changes that had a significant impact on expenditures
Nothing to report to during this reporting period

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to report to during this reporting period

6. PRODUCTS

Includes:

- The BrainPort V200 electronic vision aid (described previously) has been developed under this research. FDA clearance to market the V200 in the US is expected by early 2017.
- No inventions, patent applications, or licenses have resulted from this research.
- No other products were developed under this program

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Information for each person who has worked at least one person month per year on the project during the reporting year, regardless of compensation is outlined below.

1. Name: Patricia Grant
   Project Role: Co-PI: Lead Researcher
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 6
   Contribution to Project: Ms. Grant has been responsible for overseeing the conduct of the research to ensure consistent adherence to the study protocol across study sites. In addition, she has acted as data monitor, carefully reviewing data and data collection

activities. Lastly, Ms. Grant is also responsible for maintaining IRB and HRPO approval throughout the study.
Funding Support: N/A

2. Name: Rich Hogle
   Project Role: Co-PI – Lead Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 4
   Contribution to Project: Mr. Hogle has managed the activities of the Engineering team to ensure delivery of devices and associated software. As Lead Engineer, Mr. Hogle has been responsible for the development of the BrainPort V200 from concept through release and support of devices for this research activity.
   Funding Support: N/A

3. Name: Derald Woods
   Project Role: Software Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 6
   Contribution to Project: Mr. Woods has been responsible for the primary software development efforts related to BrainPort V200.
   Funding Support: N/A

4. Name: Ryan Pope
   Project Role: Production Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 5
   Contribution to Project: Mr. Pope has been involved with the BrainPort V200 builds, as well as the packaging and shipping activities involved with the V200 delivery to study sites.
   Funding Support: N/A

5. Name: Steve Correll
   Project Role: Electrical Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 1
   Contribution to Project: Mr. Correll has been responsible for design and implementation of the electronic hardware architecture for BrainPort V200.
   Funding Support: N/A

6. Name: Janet Szlyk
   Project Role: Site PI
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 1
   Contribution to Project: Dr. Szlyk has been responsible for the conduct of the research at the Chicago Lighthouse. Including subject recruitment, device training, documentation, and all study-related procedures.
   Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02- 5.0 calendar months

7. Name: Meesa Maeng
   Project Role: Research Associate/BrainPort Trainer

Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Ms. Maeng has been responsible for all study-related procedures at the Chicago Lighthouse, including subject recruitment and screening, device training, and data collection.
Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02 – 4.0 calendar months

8. Name: William Seiple
   Project Role: Site PI
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 2
   Contribution to Project: Dr. Seiple has been responsible for conduct of the research at the Lighthouse Guild. Including subject recruitment, device training, documentation, and all study-related procedures
   Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02 – 5.0 calendar months

9. Name: Tiffany Arrango
   Project Role: Research Associate/BrainPort Trainer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 3
   Contribution to Project: Ms. Arrango has been responsible for all study-related procedures at the Lighthouse Guild, including subject recruitment and screening, device training, and data collection.
   Funding Support: N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Tiffany Arango is no longer active study personnel.

What other organizations were involved as partners?
The partner organizations that have been involved in the project are detailed below.
Organization Name: The Chicago Lighthouse for People Who Are Blind and Visually Impaired
Location of Organization: Chicago, IL
Partner's contribution to the project (identify one or more): Facilities and collaboration (study site)

Organization Name: Lighthouse Guild
Location of Organization: New York, NY
Partner's contribution to the project (identify one or more): Facilities and collaboration (study site)

8. SPECIAL REPORTING REQUIREMENTS

The Quad Chart for this reporting period is included in Appendix A.

9. APPENDIX

Appendix A: Quad Chart

APPENDIX A.

Safety and Efficacy of the BrainPort V200 Device in Individuals Blinded by Traumatic Injury

DM130076, Assistive Technologies Research Award
W81XWH-13-DMRDP-ATRA

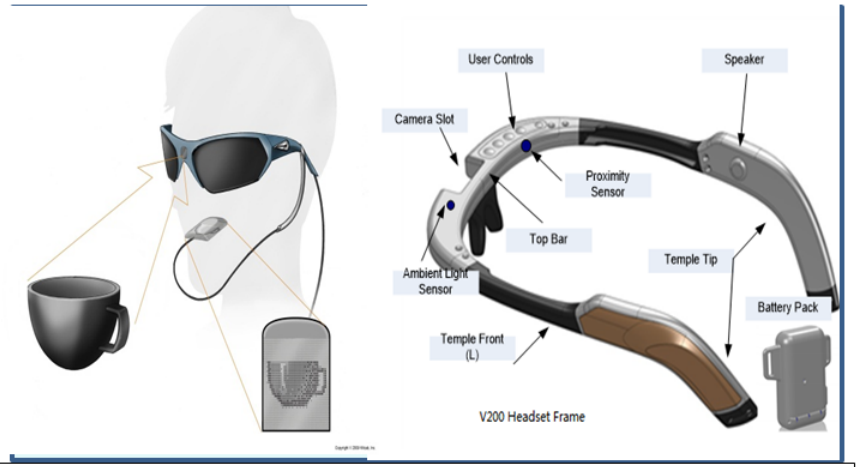
PI: Patricia Grant, M.S. **Org:** Wicab, Inc. **Award Amount:** $1,393,819.84

Study/Product Aim(s)

Aim1: Enable individuals blinded by traumatic injury to test and evaluate the BrainPort V200 device in normal operational settings (at home, public places, etc.).
Aim 2: Evaluate the safety and efficacy of the BrainPort V200 device on this population.
Aim 3: Explore the design and hardware requirements for a population with multiple disabilities (polytrauma).

Approach

Twenty subjects who are profoundly blind due to a traumatic injury will be enrolled into the study. Subjects will receive approximately 10 hours of training in the clinic setting on the BrainPort V200 device and will then be sent home with the device for 12 months to use the device in their environments. Subjects will visit the study sites quarterly to complete efficacy and safety assessments.



The BrainPort device has demonstrated safety and efficacy in individuals blinded without cortical injury. The current research is designed to assess the safety and efficacy of the device in individuals blinded by traumatic injury (i.e. TBI or ocular trauma).

Timeline and Cost

Activities / CY	14	15	16
Subject Recruitment			
Evaluation of device safety			
Evaluation of device efficacy			
Exploration of design requirements			
Estimated Budget ($K)	**$767**		**$627**

Updated: 10/24/2016

Goals/Milestones

CY14 Goal – Human subjects protocol and informed consent approval
- ☑ Finalize subject eligibility criteria and assessment measures
- ☑ NEIRB Approval

CY15 Goals – Study Site and Subject Training
- ☑ HRPO Approval
- ☑ Device hardware and software modifications implemented and evaluated
- ☑ Recruit and screen subjects
- ☑ BrainPort V200 devices and tablets distributed to subjects
- ☑ Subjects trained and pre-post training assessments completed
- ☐ Quarterly assessments evaluating safety and efficacy of device

CY16 Goal – Complete data collection, perform data analysis and reporting
- ☐ Quarterly assessments evaluating safety and efficacy of device
- ☐ Data analysis, report safety events and efficacy findings from study

Comments/Challenges/Issues/Concerns

We are 6 months behind schedule on the timeline of our study plan. We anticipated to begin & complete enrollment inY1Q3. Due to delays in completion of the V200's we did not begin enrollment until Y1Q4. In addition, due to the very specific population we aimed to enroll, recruitment continued longer than anticipated and was not complete until Y2Q2.

Budget Expenditure to Date

Projected Expenditure: $1,393,819.84
Actual Expenditure: $1,331,004.18